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IN THE UNITED STATE PATENT AND TRADEMARK OFFICE

In re the Application of: Garvey, Schroeder and Saenz de Tejada

Application No: 09/145,143 Group Art Unit: 1654

Filing Dated: September 1, 1998 Examiner: B. Celsa

Title: Nitrosated and Nitrosylated α-Adrenergic Receptor Antagonist

Compounds, Compositions and Their Uses

Docket Number: 102258.254

Assistant Commissioner of Patents Washington, DC 20231

DECLARATION UNDER 37 C. F. R. § 1.132

I, Gorm Wagner, M. D., Ph. D., declare the following.

- 1. I am currently at the National University Hospital, Copenhagen, Denmark, in the Department of Physiology, Division of Sexual Physiology. I am the past President of the International Society of Impotence Research, past President of the International Academy of Sex Research, Member of Honor of the Asia-Pacific Society for Impotence Research, founding Member of the Board of European of Federation of Sexology and the founding President of the European Society of Impotence Research. I have received 3 international awards in the area of Human Sexuality and Sexology.
- 2. I have extensive experience in the field of human sexuality and sexology, which are my major research interests. I am the founding co-editor-inchief of the International Journal of Impotence Research and have served in the capacity of editor since 1989. I am also on the editorial board of eight different international Journals that are in the field of Sexual Behavior, Sexual Medicine and Obstetrics and Gynecology. I have authored numerous publications, books and

abstracts and am also the director and producer of educational films in the field of human sexuality. A copy of my C. V. is attached hereto as Exhibit A.

- 3. I have reviewed the specification and claims of the above application, and the Office Action dated June 21, 1999, for the above application. I have also reviewed the specification and claims of parent Application No. 08/714,313, filed September 18, 1996, and grandparent Application No. 08/595,732, filed February 2, 1996 (issued as U. S. Patent No. 5,932,538).
- 4. The above application has claims directed to methods of treating human impotence in an individual by administering a therapeutically effective amount of an α -adrenergic receptor antagonist and a compound that donates, transfers or releases nitric oxide, elevates endogeneous levels of endothelium-derived relaxing factor, or stimulates nitric oxide synthesis. The above application also has claims directed to methods of treating human male impotence as well as human female impotence.
- 5. Based on the language in the specification and claims of the application, one skilled in the art would recognize that the term "human impotence" includes both human male impotence and human female impotence.
- 6. One skilled in the art would also recognize that the term "impotence" includes both males and females, based on the disclosures of Application No. 09/145,143, parent Application No. 08/714,313, and grandparent Application No. 08/595,732. All three applications provide the same doses and modes of administration for the treatment of human impotence in both males and females, by administering an α -adrenergic receptor antagonist and a compound that donates, transfers or releases nitric oxide, elevates endogeneous levels of endothelium-derived relaxing factor, or stimulates nitric oxide synthesis.
- 7. Webster's Ninth New Collegiate Dictionary, page 605, (1984), a copy of which is attached hereto as Exhibit B, defines "impotence" as "the quality or state of being impotent," and defines "impotent" as:
 - 1. a: not potent: lacking in power, strength, or vigor: HELPLESS

- b: unable to copulate; broadly: STERILE usu. used of males obs: incapable of self-restraint: UNGOVERNABLE
- 8. One skilled in the art would readily recognize that an inability "to copulate" is applicable to both males and females. Although the term impotence is mostly used for males, the term impotence clearly does not exclude females.
- 9. Taylor, F. K., Acta. Psychiat. Scand., 58:80-87 (1978), a copy of which is attached hereto as Exhibit C, specifically addresses "impotence in women" and "female impotence". The author states that impotence is "not exclusive to men" and also discusses the emotional and physiological effects of sexual response, copy of which is attached hereto.
- 10. One skilled in the art would understand that the term "impotence" includes both male impotence and female impotence based on (i) the plain language of the term "human impotence" in the above application and the priority applications, (ii) the doses and modes of administration of the compounds in the above application and the priority application, (iii) the dictionary definition of the term "impotence" and (iv) the literature in the field.
- 11. In recent years the treatment and management of sexual disorders or problems has become more prominent. As a result, this field of research has been growing very rapidly. The terms, vocabulary, management, diagnostic assessment, strategies for improving public and professional awareness and knowledge of sexual disorders and problems have been continually changing. When the inventors filed the grandparent Application No. 08/595,732, on February 2, 1996, and the parent Application No. 09/714,313, on September 18, 1996, one skilled in the art used the term "impotence" to mean and include the now commonly used term "sexual dysfunction".
- 12. To one skilled in the art in February 1996 and September 1996, the term impotence referred to and included any sexual dysfunction in males and females. These sexual dysfunctions include, but are not limited to, sexual desire dysfunctions and disorders, sexual arousal dysfunctions and disorders, orgasmic disorders, sexual

pain disorders, orgasmic dysfunction, sexual pain disorders, dyspareunia and vaginismus.

- 13. I am currently the editor-in-chief of the International Journal of Impotence Research. It is the policy of this Journal to include articles on female sexual dysfunction in the International Journal of Impotence Research.
- 14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements so made are punishable by fine or imprisonment or both, under § 1001 of Title 18 of the United States Code and that such willful statements may jeopardize the validity or enforceability of this application or any patent issued thereon.

Gorm Wagner

Date

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